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10/649,068

08/27/2003

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EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT

PAPER NUMBER

3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/649,068 | Applicant(s) MARK ET AL. | |
| | Examiner Parikha S. Mehta | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-11, 13-17, 19-21, 23-34, 36-42 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-11, 13-17, 19-21, 23-34, 36-42 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 2, 4-11, 13-17, 19-21, 23-34, 36-42 and 50 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 7 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 7 recite a target confirmation device that is only insertable within the cannula when the introducer stylet is removed from the cannula. While the specification describes a method of using the invention wherein the stylet and target confirmation device are sequentially and separately disposed within the cannula, there is no support for the limitation that the cannula can only accommodate one of the two elements at a time.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 6, 13-17, 20, 25 and 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz (US Patent No. 6,869,430), hereinafter Balbierz ('430), previously made of record.

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Regarding claims 1, 2 and 6, Balbierz ('430) teaches a tissue biopsy device including a cannula having open proximal and distal ends and an introducer for a plurality of resilient members of length longer than that of the cannula, wherein the members are removably disposed and selectively insertable within the cannula (Fig. 1, col. 5 lines 40-44, col. 16 lines 11-16). The resilient members of Balbierz ('430) constitute a stylet and a target confirmation device as claimed in the instant application. The distal ends of both the stylet and target confirmation device of Balbierz ('430) extend substantially beyond the distal end of the cannula (Fig. 1). Balbierz ('430) discloses that the cannula is configured to introduce a biopsy device (col. 5 lines 26-60). Balbierz ('430) discloses the system for use with MRI, thereby making it MRI compatible as claimed in the instant application (col. 25 line 2).

With regard the statement of intended use and other functional statements (see for example, Claim 1 line 10, "wherein the introducer stylet is used to penetrate tissue to create a pathway"), they do not impose any structural limitations on the claims distinguishable over the introducer of Balbierz ('430) (col. 5 lines 55-60), which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Balbierz ('430) does not teach that the target confirmation device is insertable within the cannula only when the introducer stylet is removed from the cannula. Applicant does not disclose that this feature solves a particular problem or provides a patentable advantage over the prior art, in which the stylet and confirmation device may be simultaneously disposed within the cannula. Furthermore, one of ordinary skill in the art would expect Applicant's invention to work equally well with either sequentially or simultaneously disposed elements. Accordingly, one of ordinary skill in the art at the time of invention would consider it an obvious matter of design choice to insert the stylet and confirmation device sequentially, as recited in claim 1, instead of simultaneously as described by Balbierz ('430).

Regarding claim 13, Balbierz ('430) teaches that the introducer can be configured to pierce tissue (col. 5 lines 55-56).

Regarding claims 14, 15 and 17, the system of Balbierz ('430) also includes a fluid conduit for delivering fluid provided in communication with the lumen, a one-way valve and a two-way valve (col.

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17 lines 37-44). The one-way valve and two-way valve of Balbierz ('430) constitute a hemostatic valve and a directional valve, respectively, as claimed in the instant application.

Regarding claim 16, Balbierz ('430) shows that the proximal end of the target confirmation device 24 engages the proximal end of the outer cannula (Fig. 2), and further states that the proximal end of the device may comprise a port or actuator (col. 6 lines 1-2), any of which would constitute the fitting interfaces claimed in the instant application.

Regarding claims 20 and 33, Balbierz ('430) provides a handpiece and a rotatable tissue-receiving opening for removing tissue from the target site (col. 17 lines 57-63).

Regarding claim 25, Balbierz ('430) shows that each of the resilient members are approximately equal in length (Fig. 1).

6. Claims 4, 5, 7-11, 19, 26, 28, 34, 42 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('430) in view of Hurtak (WO 98/55016), hereinafter Hurtak ('016), previously cited by Examiner in a prior Office Action.

Regarding claims 4, 5, 7-11, 19 and 36-39, Balbierz ('430) substantially teaches all features of the present invention as previously applied to claims 1, 2, 6, 13-17 and 20. Balbierz ('430) teaches an optical target confirmation device (col. 6 lines 16-18), but does not teach an MR-visible target confirmation device. In the same problem solving area, Hurtak ('016) teaches an MRI-compatible guidewire, equivalent to a target confirmation device, with an MRI-visible contrast band at the distal tip (p. 3 lines 14-23, Fig. 1). Hurtak ('016) teaches that the contrast band is of relatively low artifact generating material (p. 5 lines 18-21). Hurtak ('016) also provides motivation for an MRI-compatible guidewire that can be visualized without introducing significant artifact into the acquired patient image data (p. 3 lines 6-13). It would have been obvious to one of ordinary skill in the art at the time of invention to use the wire of Hurtak ('016) with the biopsy system of Balbierz ('430), in order to use MR confirmation of the target lesion instead of optical confirmation.

Regarding claim 28, by teaching that the guidewire is MRI-visible, Hurtak ('016) implicitly teaches the step of imaging the guidewire.

Regarding claims 34 and 42, Balbierz ('430) provides a rotatable tissue-receiving opening for removing tissue from the target site (col. 17 lines 57-63).

7. Claims 21, 23, 24, 27, 29-32, 41 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('430) in view of Hurtak ('016), further in view of Werne (5,782,764).

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Regarding claims 21, 23, 24 and 40, Balbierz ('430) and Hurtak ('016) substantially teach all features of the present invention as previously discussed. Balbierz ('430) and Hurtak ('016) fail to discuss the length of the target confirmation device relative to the position of a tissue receiving opening of the cutting element. In the same field of endeavor, Werne ('764) teaches a cutting element with a guidewire disposed therein (Figs. 8-10). Werne ('764) shows that the distance between the proximal and distal ends of the guidewire is approximately equal to the distance between the center of the tissue receiving opening and handpiece of the biopsy device. It would have been obvious to one of ordinary skill in the art at the time of invention to use the biopsy device/stylet arrangement of Werne ('764) with the wire of Hurtak ('016), inside the system of Balbierz ('430) in order to better visualize the end of the biopsy device in an MRI image as taught by Werne ('764).

Regarding claims 27, 29-32, 41 and 50, Werne ('764) teaches the step of imaging the target tissue prior to or contemporaneous with insertion of the stylet (Abstract). Werne ('764) additionally teaches insertion of a biopsy device within an outer cannula in order to obtain a tissue sample for further testing (Figs. 9 & 10). Although Werne ('764) does not expressly discuss aspiration of the biopsy site after resection, this step is commonly known and performed in state of the art biopsy procedures, and Balbierz ('430) additionally provides aspiration means within the system (col. 17 lines 57-58). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the system and method of Balbierz ('430), previously modified by Hurtak ('016), to include the means and steps of Werne ('764) in order to obtain a biopsy sample of the target tissue, in view of the teachings of Werne ('764).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha S. Mehta whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha S. Mehta

Examiner – Art Unit 3737



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